IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor

Douglas Roberts et al.

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For

ELECTRIC- OR MAGNETIC-FIELD BASED DETECTION OF WHEN ELECTRODE PADS HAVE BEEN HANDLED OR REMOVED FROM

THEIR PACKAGE

APPEAL BRIEF

On Appeal from Group Art Unit 3766

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded December 15, 2005 at reel 017395, frame 0792.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claim 21 has been canceled. Claims 1-20 are pending in the application. Claims 1-20 stand finally rejected by the Examiner in the Office action mailed March 3, 2009. The claims being appealed are Claims 1-20.

IV. STATUS OF AMENDMENTS

No amendments were filed in response to the final rejection mailed March 3, 2009. A Notice of Appeal has been filed concurrently with the filing of this Appeal Brief.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per independent Claims 1 and 11 is a defibrillator and method for identifying when electrodes are being handled or removed from an electrode storage compartment. In the example of Fig. 1, electrodes 180 and 182 are connected by lead wires 184 and 186 to an electrical interface 190 of an electrode compartment 160 which in turn is coupled by cables 192, 194, 196 to a defibrillator 100. Inside the compartment is a conductor 187 which in this example is embedded in the bottom of the compartment 160. When the electrodes and their lead wires are in the compartment they are in proximity to the compartment conductor 187 which sets up a capacitance between the electrodes and their wires as one plate, and the compartment conductor as the other plate. The space between these elements and/or their insulation (such as insulation around wires) provides a dielectric between the capacitor plates. The foregoing is described on page 6, lines 5-30 of the specification. An a.c. signal 212 (see Fig. 2) is applied to this capacitance by the defibrillator. When the electrodes and their wires are handled or removed from the compartment 160 as shown in Fig. 1, the plates of the capacitance are moved relative to each other, changing the capacitance. An electrode deployment detector 208 (see Fig. 2) senses a change in the capacitance and identifies that the electrodes and wires are being handled or removed from the compartment. This is described on page 7, line 5 to page 8, line 8 of the specification.

The present invention solves one of the significant problems faced by designers of automatic external defibrillators (AEDs). AEDs are designed to enable an untrained rescuer to resuscitate a victim of sudden cardiac arrest. The AED does this by issuing audible instructions to the rescuer. If the rescuer follows the instructions as they are given, the rescuer is guided to unpacking the electrodes, applying them to the patient, and pressing the shock button when the AED detects the sudden cardiac arrest condition from the victim's monitored ECG. Most of these activities by the rescuer involve unpacking and successfully applying the electrodes to the patient's chest securely and in the proper positions. But if the rescuer does not follow the instructions for the electrodes, the AED is at a loss as to what the rescuer has done and what instruction should be issued to correct an incorrect action and get the rescuer back on a successful track. Typically, the AED does not know what is happening to the electrodes until they are properly applied to the patient's chest and an ECG signal is received. So the prior art procedure has been for the AED to blindly instruct the rescuer to "check the electrodes," hoping that the rescuer will recover from his dilemma on his own.

The present invention addresses this problem by applying a small signal to the capacitance set up by the electrodes and the conductor of the electrode compartment, and monitoring the signal. When this capacitance changes, the AED is informed that the electrodes are being handled. If no change is detected, the AED can instruct the rescuer again to unpack the electrodes. When the capacitance drops to zero, the AED is informed that the electrodes have been removed from the compartment and can give an appropriate instruction such as to peel off the release liners and/or to apply the electrodes to the locations indicated on the backing of the electrodes. See page 9, lines 11-14. The sensing of these conditions is described in the paragraph spanning pages 7-8 of the specification. The present invention provides the AED with information on electrode activity during a rescue that can be used by the AED to formulate the proper corrective instruction for the rescuer.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1-4, 7, 10-14, 17 and 20 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over US Pat. appl. pub. US 2003/0055478 (Lyster et al.) in view of US Pat. 4,785,812 (Pihl et al.);

- B. Whether Claims 5, 6, 15 and 16 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Lyster et al. in view of Pihl et al. and further in view of US Pat. 6,336,047 (Thu et al.); and
- C. Whether Claims 9 and 19 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Lyster et al. in view of Pihl et al. and further in view of EP pub. 57,561 (Matthews et al.)

VII. ARGUMENT

A. Rejection of Claims 1-4, 7, 10-14, 17 and 20 under 35
U.S.C. §103(a) as being unpatentable over Lyster et al. in view of Pihl et al.

Apparatus Claim 1 calls for an electrode compartment with an attached conductor. Lyster et al. do not have this claim element. Claim 1 calls for monitoring an electrical characteristic of the capacitance created by the compartment conductor and a electrode with its lead wire. Lyster et al. do not have this claim element. Claim 1 also calls for identifying handling or removal of the electrode from the compartment based on a change in the monitored electrical characteristic. Lyster et al. do not have this claim element either.

Lyster et al. have an electrode and its wires in a storage compartment as shown in their Fig. 30. As they state in paragraph

[0243], Lyster et al. are concerned with detecting that the electrical path of the electrodes is damaged or defective, or that the hydrogel is drying out and thus the electrodes are no longer fit for use. These conditions are detected while the defibrillator is awaiting use, not while it is being used. In the first instance a failure such as a short or open circuit condition are responded to with a "REPLACE ELECTRODES IMMEDIATELY" message. See paragraph [0244]. In the latter case the defibrillator produces a "REPLACE ELECTRODES SOON" message. See paragraph [0245]. The electrodes being monitored are attached on opposite sides of a release liner as shown in Fig. 21C, with their foil electrodes forming the plates of a capacitor. The short or open circuit condition is detected by monitoring an out-of-range capacitance as stated in paragraph [0199]. The drying hydrogel condition is detected by monitoring the resistance as described in paragraphs [0208], [0214] and [0220].

There is, however, no change in the monitored resistance or capacitance when the electrodes are removed from the compartment as shown in Fig. 30 of Lyster et al. That is because the monitored circuit elements of the electrodes are in the same relative position inside the compartment and out. The concept of monitoring handling or removal of electrodes from a compartment is totally absent from Lyster et al., as are the three claim elements listed above.

This concept is missing from Pihl et al. also, as are the three listed elements of Claim 1. Pihl et al. are monitoring the impedance between the electrodes (as Lyster et al. are) for the purpose of sensing whether the electrodes are defibrillator electrodes or monitoring electrodes. If the impedance of the electrode's circuit is $30-200\Omega$, the electrode are assumed to be defibrillation electrodes and an attached defibrillator is enabled. If the electrode impedance is $300-2000\Omega$, the electrodes are assumed to be monitoring electrodes and a "monitor only" message is displayed. For all other impedance values a fault condition is assumed and the "check electrodes" message is displayed. Pihl et al. are unconcerned with monitoring the handling or removal of electrodes from an electrode compartment and are unable to sense these conditions. This is because the three elements of Claim 1 listed above are missing from Pihl et al. as they were from Lyster et al. Accordingly it is respectfully submitted that the combination of Pihl et al. and Lyster et al. cannot render Claim 1 and its dependent claims 2-10 unpatentable.

Method Claim 11 calls for an electrode storage compartment with an attached conductor. As shown by the foregoing, Lyster et al. and Pihl et al. do not have this claim element. Claim 11 calls for monitoring an electrical characteristic of the capacitance created by the compartment conductor and a electrode with its lead wire. Lyster et al. and Pihl et al.

do not have this claim element. Claim 11 also calls for identifying handling or removal of the electrode from the compartment based on a change in the monitored electrical characteristic. Lyster et al. and Pihl et al. do not have this claim element either. Accordingly it is respectfully submitted that, for the reasons presented with respect to Claims 1-10, Lyster et al. and Pihl et al. cannot render Claim 11 and its dependent Claims 12-20 unpatentable.

В. Rejection of Claims 5, 6, 15 and 16 under 35 U.S.C. §102(b) as being unpatentable over Lyster et al. in view of Pihl et al. and further in view of Thu et al.

Claims 5 and 6 depend from Claim 1 and Claims 15 and 16 depend from Claim 11. Thu et al. was cited for its showing of a circuit in use with a defibrillator that operates with two different frequencies, as does the illustrated embodiment of the electrode deployment detector of the present invention. What Thu et al. are doing is sensing the proper or improper placement of electrodes on a manikin during defibrillation training. A first frequency signal is applied to a sensor 2 located in a manikin in the location where an electrode is to be attached during training. A second frequency is applied to the area around the sensor 2. When the electrodes is attached to the manikin exactly over the sensor 2,

the ratio of the first frequency to the second frequency picked up by the electrode is at a maximum. But if the electrode is applied out of position it will overlap some of the second area and pick up a greater proportion of the second frequency signal. The ratio of the frequencies will then decline, and the lower ratio is indicated on a meter 12,14.

Thu et al. are unconcerned with detecting the handling or removal of an electrode from an electrode compartment. They are concerned with sensing whether an electrode has been placed on the proper location of a manikin during training. Like Lyster et al. and Pihl et al., Thu et al. lack the three claim elements of Claims 1 and 11 which are missing from the other two patents. Accordingly it is respectfully submitted that Claims 1 and 11 are patentable over Lyster et al., Pihl et al., and Thu et al., as are their dependent Claims 5, 6, 15 and 16.

C. Rejection of Claims 9 and 19 under 35 U.S.C. §103(a) as being unpatentable over Lyster et al. in view of Pihl et al. and further in view of Matthews et al.

Claim 9 depends from Claim 1 and Claim 19 depends from Claim
11. Lyster et al. and Pihl et al. have been discussed above and have been seen to lack three elements of Claims 1 and 11. Matthews et al. is similarly lacking.

Matthews et al. was cited for its showing of a multiplexer which sequentially applies a signal to ones of a group of electrodes. The electrodes in question are muscle stimulator electrodes and the multiplexer (9, 15-18) is part of a muscle stimulator which applies a stimulation signal to each one of a group of electrodes (W-Z) in sequence. Like Lyster et al. and Pihl et al., Matthews et al. are unconcerned with identifying whether electrodes are being handles or removed from an electrode compartment. Matthews et al. also lack the three claim elements of both Claim 1 and Claim 11 which were shown to be lacking from Lyster et al. and Pihl et al. Like the other two patents, Matthews et al. do not have an electrode compartment with an attached conductor. Matthews et al. do not monitor an electrical characteristic of the capacitance created by the compartment conductor and an electrode and lead wire. Matthews et al. also do not identify the handling or removal of an electrode from a compartment based on a change in the monitored electrical characteristic. For these reasons it is respectfully submitted that the combination of Lyster et al., Pihl et al., and Matthews et al. cannot render Claims 1 and 11 and their dependent Claims 9 and 19 unpatentable.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1-4, 7, 10-14, 17 and 20 are patentable over Lyster et al. and Pihl et al., that Claims 5, 6, 15 and 15 are patentable over Lyster et al. and Pihl et al. in view of Thu et al., and that Claims 9 and 10 are patentable over Lyster et al. and Pihl et al. in view of Matthews et al. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of these claims stated in the March 30, 2009 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 1-20 are the claims involved in the appeal.

1. (rejected) A defibrillator apparatus comprising: an electrode with attached lead wire; an electrode compartment with an attached conductor; a source of alternating current; and an electrode deployment detector configured for:

monitoring a magnitude of an electrical characteristic measured from an electrical circuit having from said source an alternating electric current path that includes said electrode with attached lead wire, said conductor, and a space or other electrical insulator intervening between said conductor and said electrode with attached lead wire, said compartment conductor being disposed in proximity of said electrode with attached lead wire to create capacitance in said electrical circuit; and

identifying, based on a change of said magnitude, an occurrence of at least one of handling of said electrode with attached lead wire and removing of said electrode with attached lead wire from the compartment.

- 2. (rejected) The apparatus of claim l, wherein said electrical circuit is configured so that said magnitude varies with said capacitance.
- 3. (rejected) The apparatus of claim 1, wherein said electrical circuit includes an integrator in series with said capacitance.
- 4. (rejected) The apparatus of claim 3, wherein said electrical circuit further includes a rectifier for rectifying input voltage to the integrator.
- 5. (rejected) The apparatus of claim 1, wherein said source periodically shifts between different frequencies of alteration.

6. (rejected) The apparatus of claim 5, wherein said electrical circuit is configured so that said magnitude varies with said capacitance; and

wherein said electrode deployment detector is configured to perform said identifying based on at least one of a sum and a difference between measurements of said magnitude that correspond to respective ones of said frequencies.

- 7. (rejected) The apparatus of claim 1, wherein the alternating electric current path further includes another electrode and attached lead wire.
- 8. (rejected) The apparatus of claim 7, wherein the alternating electric current path further comprises an electrically conductive medium disposed between the electrodes that provides a pathway for flow of electric current from one of the lead wires to the other by means of the electrodes and said medium.
- 9. (rejected) The apparatus of claim 8, wherein activation of a source for the electric current from one of the lead wires to the other and activation of said source of alternating current are alternated in a time division manner.
- 10. (rejected) The apparatus of claim 1, comprising a defibrillator that is configured to issue a sequence of user prompts and to advance from a particular one of the user prompts to a next one of the user prompts upon said identifying.
- 11. (rejected) A method of detecting when a defibrillator electrode has been handled or removed from a storage compartment comprising the steps of:

monitoring a magnitude of an electrical characteristic measured from an electrical circuit having from an alternating current source an alternating electric current path that includes an electrode with attached lead wire, a conductor attached to the storage compartment, and a space or other electrical insulator intervening between said conductor and said

electrode with attached lead wire, said conductor being disposed in proximity of said electrode with attached lead wire when the electrode is stored in the compartment to create capacitance in said electrical circuit; and

identifying, based on said magnitude, an occurrence of at least one of handling of said electrode with attached lead wire and removing said electrode with attached lead wire from the storage compartment.

- 12. (rejected) The method of claim 11, wherein said electrical circuit is configured so that said magnitude varies with said capacitance.
- 13. (rejected) The method of claim 11, wherein monitoring further comprises monitoring a magnitude of an electrical characteristic measured from an electrical circuit which includes an integrator in series with said capacitance.
- 14. (rejected) The method of claim 13, wherein monitoring further comprises monitoring a magnitude of an electrical characteristic measured from an electrical circuit which further includes a rectifier for rectifying input voltage to the integrator.
- 15. (rejected) The method of claim 11, wherein said source periodically shifts between different frequencies of alternation.
- 16. (rejected) The method of claim 15, wherein said electrical circuit is configured so that said magnitude varies with said capacitance, and wherein the identifying step performs said identifying based on at least one of a sum and a difference between measurements of said magnitude that correspond to respective ones of said frequencies.
- 17. (rejected) The method of claim 11, wherein monitoring further comprises monitoring a magnitude of an electrical characteristic measured from an electrical circuit having said alternating current path which further includes another electrode and attached lead wire.

- 18. (rejected) The method of claim 17, wherein monitoring further comprises monitoring a magnitude of an electrical characteristic measured from an electrical circuit having said alternating current path which further comprises an electrically conductive medium disposed between the electrodes that provides a pathway for flow of electric current from one of the lead wires to the other by means of the electrodes and said medium.
- 19. (rejected) The method of claim 18, wherein monitoring further comprises activating a source for the electric current from one of the lead wires to the other in a time division manner with the activation of said source of alternating current.
- 20. (rejected) The method of claim 11, further comprising the step of issuing a sequence of user prompts, the issuing step including the step of advancing from a particular one of the user prompts to a next one of the user prompts upon said identifying.

21. (canceled)

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.